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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,470	03/20/2006	Henry Chiu	P1976R1	2152

9157 7590 02/05/2008

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	PAPER NUMBER
1647	
MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,470	CHIU ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/29/2005 and 09/11/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 2-8) and of the specie of Seq. Id. No. 17 in the reply filed on 11/27/2007 is acknowledged. Claims 1, 9-28 were cancelled and claims 2-4 were amended in the amendment filed 11/27/2007. Claims 2-8 are currently examined.

Claim Rejections - 35 USC § 101 and 35 USC § 1122-8

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 2-8 are directed to an isolated nucleic acid having at least 80%, a nucleic acid sequence SEQ ID NO: 17. The claims also recite a vector and host

cell as well as a method of obtaining the protein encoded by the nucleic acid claimed from the host cell transfected with the said nucleic acid.

The specification discloses compositions and methods useful for the diagnosis and treatment of immune related disease in mammals, including humans. The specification presents proteins (including agonist and antagonist antibodies) which are a result of stimulation of the immune response in mammals. However, the instant specification does not teach any significance or functional characteristics of the polynucleotide (SEQ ID NO: 17); no polypeptide encoded by the claimed nucleic acid is disclosed. The specification also does not disclose any methods or working examples that indicate the polynucleotides and putative polypeptide of the instant invention are involved in any activity. There is no biological activity, expression pattern, phenotype, disease or condition, ligand, binding partner, or any other specific feature that is disclosed as being associated with the putative protein encoded by the polynucleotide of Seq. Id. No. 17 or with the polynucleotide per se. Without any information as to the specific properties of polynucleotide of Seq. Id. No. 17 or the polypeptide encoded by it, the mere identification of the polynucleotide is not sufficient to impart any particular utility to the claimed polynucleotides. Since significant further research would be required of the skilled artisan to determine how the claimed polynucleotide and polypeptide are involved in any activities, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification does not present any specific property of the polynucleotide. Additionally, at page 69 of the specification, it is

disclosed that the nucleic acid of Seq. Id. No.: 17 is upregulated upon stimulation with anti-CD40/IL-4 of B-cells. However, the role of the sequence or of the protein that it encodes is not disclosed and is not predictive of any particular disease or condition. The process of assessing the putative correlation between a disease and the nucleic acid claimed would require significant further research and the extent to which this information can be used for diagnostic or therapeutic purposes as stated in the specification on page 68 and thus the implicitly asserted utility is not substantial.

4. Claims 2-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

However, even if the claimed invention is eventually deemed to have a credible, specific and substantial asserted utility or a well established utility, claims 2-8 would remain rejected under 35 U.S.C. § 112, first paragraph. The specification discloses that a polynucleotide which has at least about 80% nucleic acid sequence identity with a nucleotide acid sequence of Seq. Id. No.: 17 . However, the specification does not teach any variant, fragment, or derivative of the nucleic acid other than the full-length nucleic acid sequence of SEQ ID NO: 17. The specification also does not teach functional or structural characteristics of the nucleic acid variants recited in the claims.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid

substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the DNA and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997,

Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Due to the large quantity of experimentation necessary to generate the large number of derivatives recited in the claims and possibly screen the same for activity; the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity; the absence of working examples directed to same; the complex nature of the invention; the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure; and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. The specification is enabling only for the polynucleotide of Seq. Id. No.: 17.

5. Claims 2-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an isolated nucleic acid having at least 80%, a nucleic acid sequence SEQ ID NO: 17. The claims also recite a vector and host cell as well as a method of obtaining the protein encoded by the nucleic acid claimed from the host cell transfected with the said nucleic acid.

The claims do not require that the nucleic acid or the putative polypeptide encoded by it to possess any particular biological activity, nor any particular conserved

structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of one polynucleotide species (SEQ ID NO: 17) and is not adequate written description of an entire genus of functionally equivalent polynucleotides with at least 80% sequence identity to a nucleic acid comprising the sequence of SEQ ID NO:17.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only an isolated nucleic acid consisting of the sequence of SEQ ID NO: 17 but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 2-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (U. S. Pat. No. 6,812,339).

Venter et al. teach a DNA sequence (Seq. Id. No.: 15960- Table 1) that is 98.5% identical with the Seq. Id. No.:17 of the instant Application (see below:

```
GenCore version 6.2.1
                  Copyright (c) 1993 - 2008  Biocceleration Ltd.


OM nucleic - nucleic search, using sw model

Run on:         January 23, 2008, 12:42:08 ; Search time 365 Seconds
                                           (without alignments)
                                           5776.095 Million cell updates/sec

Title:          US-10-527-470-17
Perfect score:  537
Sequence:       1 ggcattcctggcagagggaa.........attcagtggaaaaaaaaaa 537

Scoring table:  IDENTITY_NUC
                Gapop 10.0 , Gapext 1.0

Searched:       5378416 seqs, 1963011933 residues

Total number of hits satisfying chosen parameters:      10756832

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
                 Maximum Match 100%
                 Listing first 45 summaries

Database :        Issued_Patents_NA:*
                 1:  /ABSS/Data/CRF/ptodata/2/ina/1_COMB.seq:*
                 2:  /ABSS/Data/CRF/ptodata/2/ina/5_COMB.seq:*
                 3:  /ABSS/Data/CRF/ptodata/2/ina/6A_COMB.seq:*
                 4:  /ABSS/Data/CRF/ptodata/2/ina/6B_COMB.seq:*
                 5:  /ABSS/Data/CRF/ptodata/2/ina/7A_COMB.seq:*
                 6:  /ABSS/Data/CRF/ptodata/2/ina/7B_COMB.seq:*
                 7:  /ABSS/Data/CRF/ptodata/2/ina/H_COMB.seq:*
                 8:  /ABSS/Data/CRF/ptodata/2/ina/PCTUS_COMB.seq:*
                 9:  /ABSS/Data/CRF/ptodata/2/ina/PP_COMB.seq:*
                 10:  /ABSS/Data/CRF/ptodata/2/ina/RE_COMB.seq:*
                 11:  /ABSS/Data/CRF/ptodata/2/ina/backfiles1.seq:*

      Pred. No. is the number of results predicted by chance to have a
      score greater than or equal to the score of the result being printed,
      and is derived by analysis of the total score distribution.

                                    SUMMARIES

                  %
Result            Query
   No.   Score    Match Length DB  ID                          Description
```

	1	528.8	98.5	22010	3	US-09-949-016-15960	Sequence 15960, A
	2	99.2	18.5	364	3	US-09-771-161A-17	Sequence 17, Appl
	3	66.6	12.4	7218	2	US-08-232-463-14	Sequence 14, Appl
	4	51.6	9.6	828	7	US-09-925-065A-5061	Sequence 5061, Ap
c	5	50.2	9.3	648	7	US-09-925-065A-934325	Sequence 934325,
c	6	50.2	9.3	648	7	US-09-925-065A-952443	Sequence 952443,
c	7	49.8	9.3	1683	7	US-09-925-065A-66441	Sequence 66441, A
c	8	49.6	9.2	601	3	US-09-949-002-3764	Sequence 3764, Ap
c	9	49.6	9.2	601	3	US-09-949-002-3765	Sequence 3765, Ap
c	10	49.6	9.2	601	3	US-09-949-002-3766	Sequence 3766, Ap
c	11	49.6	9.2	601	3	US-09-949-002-7640	Sequence 7640, Ap
c	12	49.6	9.2	601	3	US-09-949-002-7641	Sequence 7641, Ap
c	13	49.6	9.2	601	3	US-09-949-002-7642	Sequence 7642, Ap
	14	49.6	9.2	55068	3	US-09-949-002-691	Sequence 691, App
	15	49.6	9.2	55068	3	US-09-949-002-778	Sequence 778, App
	16	49.6	9.2	72048	3	US-09-949-002-600	Sequence 600, App
	17	49.6	9.2	72048	3	US-09-949-002-684	Sequence 684, App
	18	49	9.1	569	7	US-09-925-065A-152496	Sequence 152496,
	19	48.6	9.1	262	3	US-09-573-080A-99	Sequence 99, Appl
	20	48.6	9.1	262	5	US-09-854-867-99	Sequence 99, Appl
c	21	48.6	9.1	36652	3	US-09-949-016-14683	Sequence 14683, A
c	22	47.6	8.9	627	7	US-09-925-065A-865141	Sequence 865141,
c	23	47.6	8.9	627	7	US-09-925-065A-865142	Sequence 865142,
c	24	47.6	8.9	627	7	US-09-925-065A-898857	Sequence 898857,
	25	47	8.8	10396	3	US-09-949-016-15573	Sequence 15573, A
	26	46.8	8.7	50	3	US-10-131-827-4990	Sequence 4990, Ap
	27	46.8	8.7	50	5	US-10-131-831-4990	Sequence 4990, Ap
	28	46.8	8.7	50	5	US-10-325-899-4990	Sequence 4990, Ap
c	29	46.8	8.7	596	7	US-09-925-065A-612806	Sequence 612806,
c	30	46.8	8.7	596	7	US-09-925-065A-612807	Sequence 612807,
c	31	46.6	8.7	58768	3	US-09-949-016-13175	Sequence 13175, A
c	32	46.4	8.6	607	7	US-09-925-065A-161787	Sequence 161787,
c	33	46.4	8.6	11577	3	US-09-949-016-14662	Sequence 14662, A
	34	46.4	8.6	55703	3	US-09-949-016-12007	Sequence 12007, A
	35	46.4	8.6	55703	3	US-09-949-016-16781	Sequence 16781, A
c	36	46.2	8.6	804	7	US-09-925-065A-712208	Sequence 712208,
c	37	46.2	8.6	804	7	US-09-925-065A-712209	Sequence 712209,
	38	46.2	8.6	36387	3	US-09-949-016-12370	Sequence 12370, A
	39	46.2	8.6	36387	3	US-09-949-016-13862	Sequence 13862, A
	40	46	8.6	601	3	US-09-949-016-48479	Sequence 48479, A
	41	46	8.6	81384	3	US-09-949-016-12422	Sequence 12422, A
	42	46	8.6	91933	3	US-09-949-016-11855	Sequence 11855, A
	43	46	8.6	91933	3	US-09-949-016-14628	Sequence 14628, A
c	44	45.8	8.5	662	7	US-09-925-065A-516143	Sequence 516143,
	45	45.8	8.5	719	7	US-09-925-065A-53340	Sequence 53340, A

ALIGNMENTS

RESULT 1
US-09-949-016-15960
; Sequence 15960, Application US/09949016

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; Patent No. 6812339
; GENERAL INFORMATION:
;  APPLICANT: VENTER, J. Craig et al.
;  TITLE OF INVENTION: POLYMORPHISMS IN KNOWN GENES ASSOCIATED
;  TITLE OF INVENTION:  WITH HUMAN DISEASE, METHODS OF DETECTION AND USES
THEREOF
;  FILE REFERENCE: CL001307
;  CURRENT APPLICATION NUMBER: US/09/949,016
;  CURRENT FILING DATE:  2000-04-14
;  PRIOR APPLICATION NUMBER: 60/241,755
;  PRIOR FILING DATE: 2000-10-20
;  PRIOR APPLICATION NUMBER: 60/237,768
;  PRIOR FILING DATE: 2000-10-03
;  PRIOR APPLICATION NUMBER: 60/231,498
;  PRIOR FILING DATE: 2000-09-08
;  NUMBER OF SEQ ID NOS: 207012
;  SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 15960
;   LENGTH: 22010
;   TYPE: DNA
;   ORGANISM: Human
US-09-949-016-15960

  Query Match             98.5%;  Score 528.8;  DB 3;  Length 22010;
  Best Local Similarity   99.6%;  Pred. No. 3.5e-158;
  Matches  530;  Conservative    0;  Mismatches    2;  Indels    0;  Gaps
0;

Qy          1 GGCATTCCTGGCAGAGGGAACAGCATGCCAAGCGTGAGAAGGCTCAGAGTAAGGAGGTTA 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      21115 GGCATTCCTGGCAGAGGGAACAGCATGCCAAGCGTGAGAAGGCTCAGAGTAAGGAGGTTA
21174

Qy         61 AGAGCCCAAGTATTGGAGCCTACAGTTTTGCCCCTTCCATGCAGTGTGACAGTGGGCAAG
120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      21175 AGAGCCCAAGTATTGGAGCCTACAGTTTTGCCCCTTCCATGCAGTGTGACAGTGGGCAAG
21234

Qy        121 TTCCTTTCCCTCTCTGGGTCTCAGTTCTGTCCCCTGCAAAATGGTCAGAGCTTACCCCTT
180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      21235 TTCCTTTCCCTCTCTGGGTCTCAGTTCTGTCCCCTGCAAAATGGTCAGAGCTTACCCCTT
21294

Qy        181 GGCTGTGCAGGGTCAACTTTCTGACTGGTGAGAGGGATTCTCATGCAGGTTAAGCTTCTG
240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      21295 GGCTGTGCAGGGTCAACTTTCTGACTGGTGAGAGGGATTCTCATGCAGGTTAAGCTTCTG
21354

Qy        241 CTGCTCCTCCTCACCTGCAAAGCTTTTCTGCCACTTTTGCCTCCTTGGAAAACTCTTATC
300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db      21355 CTGCTCCTCCTCACCTGCAAAGCTTTTCTGCCACTTTTGCCTCCTTGGAAAACTCTTATC
21414

Qy        301 CATCTCTCAAAACTCCAGCTACCACATCCTTGCAGCCTTCCCTCATATACCCCCACTACT
360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      21415 CATCTCTCAAAACTCCAGCTACCACATCCTTGCAGCCTTCCCTCATATACCCCCACTACT
21474

Qy        361 ACTGTAGCCCTGTCCTTCCCTCCAGCCCCACTCTGGCCCTGGGGCTGGGGAAGTGTCTGT
420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      21475 ACTGTAGCCCTGTCCTTCCCTCCAGCCCCACTCTGGCCCTGGGGCTGGGGAAGTGTCTGT
21534

Qy        421 GTCCAGCTGTCTCCCCTGACCTCAGGGTTCCTTGGGGGCTGGGCTGAGGCCTCAGTACAG
480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      21535 GTCCAGCTGTCTCCCCTGACCTCAGGGTTCCTTGGGGGCTGGGCTGAGGCCTCAGTACAG
21594

Qy        481 AGGGGGCTCTGGAAGTGTTTGTTGACTGAATAAAGGAATTCAGTGGAAAAAA 532
              |||||||||||||| |||||||||||||||||||||||||||||||||| |
Db      21595 AGGGGGCTCTGGAAATGTTTGTTGACTGAATAAAGGAATTCAGTGGAAAAGA 21646
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Venter et al. also teach polymorphic, SNP-containing, nucleic acid sequences that encode variants of the human disease associated gene product (protein) disclosed herein (Table 1 and the Sequence Listing) (col.10 lines 30-35). The isolated variant proteins can be purified from cells that naturally express it, purified from cells that have been altered to express it (recombinant), or synthesized using known protein synthesis methods. A nucleic acid molecule containing SNP(s) encoding the variant protein is cloned into an expression vector, the expression vector introduced into a host cell and the variant protein expressed in the host cell. The variant protein can then be isolated from the cells by an appropriate purification scheme using standard protein purification techniques (col. 11, lines 40-50).

Thus, the sequence of Venter et al. anticipates the DNA sequence having at least 80% identity with the Seq. ID. No.:17 of the instant Application and the methods of obtaining a protein encoded by the sequence as well as the protein per se..

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/

Primary Examiner, Art Unit 1647